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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,876	05/01/2001	Vahid Saadat	509192000100	5006

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EXAMINER

IZAGUIRRE, ISMAEL

ART UNIT PAPER NUMBER

3765

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/846,876

Applicant(s)

SAADAT, VAHID

Examiner

Ismael Izaguirre

Art Unit

3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-57 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11, 13-23, 31-33 and 35-37 is/are rejected.
- 7) ☒ Claim(s) 8, 10, 12, 24-30 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
  - 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Examiner is appreciative of the changes made to the specification and the language of the claims. These have been duly noted and considered.

### ***CLAIMS***

#### ***Summary***

Claims 1 and 38 are the independent claims under consideration in this Office Action.

Claims 2-37 and 39-57 are the dependent claims under consideration in this Office Action.

#### ***Claim Language***

Concerning the language of the claims, after a further scrutiny of this, the following is submitted for applicant's consideration:

#### ***Claim Rejections - 35 U.S.C. § 112***

Claim 23 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to this claim, this claim includes the trademark "Kraton". The proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. This trademark does not define a specific structure for the membrane material. The trademark defines a particular product and this can change depending on the manufacturers desires. Accordingly, Kraton is indefinite.

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*Claim Patentability*

Concerning the Patentability of the claims, the following is submitted for Applicant's consideration:

*Claim Rejections - 35 U.S.C. § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,4,6,7,9,11,13-15,21-23,31-33,35 and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gianturco (5,334,210).

Gianturco teaches an embolizing device for insertion into an aneurysm including at least one self-expanding coil member configured to pass through at least one orifice of a membrane and be sealed within the membrane. Gianturco teaches the membrane comprising a distensible bag formed of a diamond shape when expanded and including at least one orifice for allowing connection with a catheter 12 and the insertion of the self-expanding member 18. The self-expanding member consists of a wire with a hooked end. As the wire is pushed (stimulated) through the catheter the said end is compressed and when the wire exits the catheter it expands and forms the hook end using it's "memory" characteristics for filling the diamond shaped membrane. The bag is connected to the delivering device using a mechanical joint which is disconnected once the bag is properly in place and expanded.

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Claims 1-4,13-23,31-33, and 35-37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jeffree (WO 99/03404).


Jeffree teaches an embolizing device for insertion into an aneurysm including at least one self-expanding member configured to pass through at least one orifice of a membrane and be sealed within the membrane. Jeffree teaches the membrane comprising a distensible bag formed of Lycra (which is a tradename for, which is comprised of polyurethane). The bag includes at least one orifice for allowing connection with a delivery device 14 and the insertion of the self-expanding member 18. The self-expanding member consists of a wire having memory characteristics. As the wire is pushed (stimulated) through the delivery device the wire exits the catheter and enters at least one orifice in the bag where it expands and fills the distensible bag. The bag is further taught as including at least a plurality of orifices allowing blood to pass through the bag walls. The bag is connected to the delivering device using a mechanical joint which is disconnected once the bag is properly in place and expanded. The joint is disconnected by the application of an electrical energy after the bag is located and expanded as desired.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jeffree as applied to the claims above, and further in view of Mazzocchi (WO 97/26939).

Jeffree discloses the invention substantially as claimed. See above for specific structural details. Briefly, Jeffree teaches an embolizing device for insertion in aneurysm including a self-expanding member within a distensible membrane. Jeffree teaches the self-expanding member including a metal wire having "memory" characteristics. However, Jeffree does not teach the wire comprising a Nickel Titanium alloy.

Mazzocchi teaches a occlusion device for an aneurysm formed of a self-expanding metal mesh comprising a Nickel Titanium alloy.

It would have been obvious to a person having ordinary skill in the art of occluders at the time of applicant's invention to construct the wire of Jeffree as including NiTi. Providing such wire would allow the proper "memory" characteristics. Further, the composition would allow the wire to not interact with the chemical make up of the human body and thus not cause adverse effects.

*Allowable Subject Matter*

Claims 38-57 are allowable over the art of record.

Claims 8,10,12,24-30 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*INQUIRIES*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Ismael Izaguirre located in CP2-4B18 whose telephone number is (703) 308-0892. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

A handwritten signature in black ink, appearing to read 'Ismael Izaguirre', with a long horizontal flourish extending to the right.

**Ismael Izaguirre**  
*Primary Examiner*  
*Art Unit 3765*

II  
January 16, 2003